OCT 15 2003

K031732

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI® Acumen Surgical Navigation System is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** EBI, L.P. **Contact Person:** Jon Caparotta
   100 Interpace Parkway Tel: (973) 299-9300,x3964
   Parsippany, NJ 07054

   Date prepared: 8/18/03

2. **Proprietary Name:** EBI® Acumen Surgical Navigation System
   Common Name: Instrumentation, Stereotaxic
   Classification Name: Stereotaxic Instrument (21CFR 882.4560)

3. **Predicate or legally marketed* devices that are substantially equivalent:**

Voyager Linux	(K023975)
FluroLab Plus	(K013025)
Z-Box	(K030764)

4. **Description of the device:** The EBI® Acumen Surgical Navigation System includes general instrumentation that is utilized with application specific software developed and supplied by Z-Kat, Inc., Hollywood, FL.

   Passive markers(spheres) are attached onto the Acumen instrumentation. An infrared light source generated by the camera refects off the passive markers to allow their position and orientation to be identified. The Acumen instruments are used as: 1) an independent instrument, 2) connected to instruments, which are attached to the patient, or 3) connected to the associated implant preparation and insertion instrumentation.

   All Acumen instruments will have a minimum of three (3) passive markers to be tracked by the camera. They will be rigidly connected to the instrumentation utilized in the surgical procedure and will have a defined geometry of the passive marker position for a unique identification by the camera and software system.

   The instruments can be utilized in spine and trauma procedures and are designed as single use components.

5. **Intended Use:** The EBI Acumen™ Surgical Navigation System is intended to assist the surgeon in accurately locating anatomical structures during open or percutaneous orthopedic surgical procedures. The EBI Acumen™ System is indicated for use in spine and trauma procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT or MRI based model, fluoroscopy or an imageless model of the anatomy.

6. **Materials:** The instruments are manufactured from: ABS Thermoplastic Polymer (Acrylonitrile Butadiene Styrene), Stainless Steel, Aluminum Alloy, Dupont Hytrel #5526 Natural, Loctite, Rigid PVC Clear Film, Reflective Material – Silver Transfer Film, 410 or 420 Stainless Steel.

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7. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the EBI® Acumen Surgical Navigation System and other Systems currently on the market. It is substantially equivalent* to the predicate device(s) in technological characteristics and intended use. Software verification and validation was performed to establish substantial equivalence to the predicate systems.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2003

Mr. Jon Caparotta, RAC
Manager, Regulatory Affairs
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K031732
Trade/Device Name: EBI Acumen™ Surgical Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: HAW
Dated: August 20, 2003
Received: August 21, 2003

Dear Mr. Caparotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

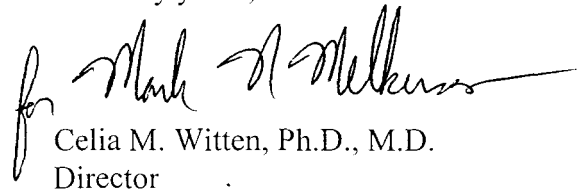
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K031732

Device Name: EBI® Acumen™ Surgical Navigation System

Indications For Use:

The EBI® Acumen™ Surgical Navigation System is intended to assist the surgeon in accurately locating anatomical structures during open or percutaneous orthopedic surgical procedures. The EBI® Acumen™ Surgical Navigation System is indicated for use in spine and trauma procedures, in which the use of stereotaxic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT or MRI based model, fluoroscopy or an imageless model of the anatomy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031732